



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/391,053 09/07/99 ROBL

J LA24A

EXAMINER

023914 HM12/0321

MARLA J MATHIAS
BRISTOL-MYERS SQUIBB COMPANY
PATENT DEPARTMENT
P O BOX 4000
PRINCETON NJ 08543-4000

BAHAR, M

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

03/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/391,053

Applicant(s)

ROBL ET AL.

Examiner

Mojdeh Bahar

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on December 18, 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 and 14-15 in part; 12,13 and 16-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 14 and 15 in part is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

Applicant's response filed December 18, 2000 to the restriction requirement submitted November 14, 2000 is acknowledged.

Applicant's election with traverse of the invention of Group IA employing a compound having an oxazole or analogous ring and the compound specie represented by the structure at the top of page 2 in Paper No. 10 submitted December 18, 2000 is acknowledged. The traversal is on the ground(s) that one skilled in the art would reasonably expect an anti-diabetic agent to also be useful in treating other disorders herein including insulin resistance, hyperglycemia, hyperinsulinemia, elevated fatty acids or glycerol, hypertriglyceridemia and obesity.

These disorders all represent separate areas of medical technology having a different field of search and are distinct one from the other as discussed in then restriction requirement mailed November 14, 2000, for example that obesity and diabetes are routinely treated differently. Anorectic agents are known to be useful in treating obesity whereas they are not routinely used in the treatment of diabetes. Insulin and Metformin are among the drugs routinely used in treating diabetes, however none of these drugs is routinely used in the treatment of obesity, See USP Dictionary of USAN and International Drugs pages 787 and 792.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-11 and 14-15 are withdrawn from consideration in part, insofar as they are drawn to an invention other than Group I as being drawn to a non elected invention and specie.

Claims 16-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Claims 12-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected specie.

Claims 1-11 and 14-15 are examined on the merits herein in so far as they read on the elected invention and specie.

Applicants' particular remarks regarding the Felber et al. reference submitted with Paper no. 10 regarding the asserted relationship amongst disorders herein have been considered but are not persuasive. Medical disorders encompassed by the claims are routinely treated differently and it is therefore not seen that one of skill in the art would expect them to all be treatable by a single method.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The parenthetical expression "(in)" in line 3 renders the claim indefinite as to whether the term "(in)" is intended to further limit the claim.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1617

The terms "discrete pocket and "roughly" in claim 5 are relative terms which renders the claim indefinite. The term "roughly" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention as to the interaction or binding site of the protein.

The expression "hydrogen bond donator or acceptor" in claims 3 and 4 is vague and indefinite in that it is not clearly understood by the Skilled Artisan. It is important to note that Bronsted-Lowry defines acids as proton donors and bases as proton acceptors. Additionally, a Lewis acid is an electron acceptor and a Lewis base is an electron donor. Organic Chemistry, 2nd edition pages 26 and 32. Therefore, describing an aP2 inhibitor a compound as a "hydrogen bond donor or acceptor" is unclear and indefinite as to what exactly is being donated or accepted by the compound.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 and 14-15 in part are rejected under 35 U.S.C. 103(a) as being unpatentable over Hotamisligil et al. in view of Failli et al. (USPN 5,218,124) as disclosed in the specification beginning at the top of page 4.

Hotamisligil et al. teaches that aP2 deficient mice do not develop diabetes, see abstract.

Art Unit: 1617

Hotamisligil et al. does not teach that the elected oxazole compound specie is an aP2 inhibitor.

Failli et al. (USPN 5,218,124) teaches that oxazole derivative compounds including the elected compound herein are known aP2 inhibitors.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the elected oxazole derivative compound herein in a method for the treatment of diabetes.

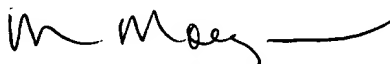
One of ordinary skill in the art would have been motivated to employ this oxazole compound in a method of treating diabetes since it is a known aP2 inhibitor. Therefore, it would be reasonably expected to be therapeutically useful in the treatment of diabetes similar to any other compound which reduces or antagonizes aP2 activity.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
March 9, 2001


MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600